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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,552	01/26/2006	Gerd Wallukat	102530-7	7096

27387 7590 09/17/2008

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EXAMINER
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ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
09/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/536,552	WALLUKAT, GERD	
	Examiner	Art Unit	
	David A. Saunders	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25 and 30-35* is/are pending in the application.

4a) Of the above claim(s) *16-25,30,31,33 and 34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15,32 and 35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 May 2005* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

AMENDMENT ENTRY

Amendment of 12/5/07 has been entered. Claims 1-25, 30-35 are pending. Claims 1-15, 32 and 35 are under examination.

RESPONSE TO ELECTION/RESTRICTION

Applicant's election without traverse of Group I (claims 1-15, 32 and 35) in the reply filed on 6/13/08 is acknowledged. Applicant's election of the peptide species as ARRCYND (SEQ ID NO:3) in the reply filed on 6/13/08 is acknowledged. Applicant's election of the disease species as "dilatative cardiomyopathy" (as recited in the response)/ "dilatative myocardiopathy" (as recited in most of the claims) in the reply filed on 6/13/08 is acknowledged.

Claims 1-15, 32 and 35 are under examination. Claim 32 will be examined for the embodiment of "diagnosis". It is considered that this embodiment of "diagnosis" involves "the step of using" a "Peptide selected from the group comprising" the peptides listed in part "a)".

OBJECTION(S) TO THE DRAWINGS

The drawing is objected to because recitation of "Figur 1" should appear as –Figure 1--. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New

Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawing will not be held in abeyance.

OBJECTION(S) TO DISCLOSURE

The disclosure is objected to because of the following informalities:

At page 12, the listing of peptides shows the sequences ARRCYND, PKCCDF listed for both the "I loop" and "II loop" of beta-1 myocard. How do both of "I loop" and "II loop" have the same sequence?

Pages 12-13 recite numerous peptide sequences without SEQ ID NOS.

Appropriate correction is required.

OBJECTION(S) TO CLAIMS

Claim 8 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 8 recites every possible IgG subclass, or combination thereof, encompassed by claim 1.

Claims 12, 32 and 35 are objected to because of the following informalities: SEQ ID numbering of the recited peptide sequences is required.

REJECTION(S) UNDER 35 USC 112, SECOND PARAGRAPH

Claims 1-15, 32 and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, step b) "the precipitated fraction" lacks antecedent basis.

Regarding claim 1, step b), the phrase "particularly one" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

In claim 1, step d) “the materials” lack antecedent basis.

In claim 1, step e) it is believed that “whereby” was intended to be recited as –wherein--.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are:

1) There is no nexus between the “denaturing agent” of step a) and the “precipitated fraction” of step b). What gets denatured, what gets precipitated?

2) There is no nexus between the "Incubating” of step c) and the “Washing” of step d). What is one “Washing”? Is one “washing” off components of the “mixture” that have not become bound to the “carrier” in step c)? How would such binding occur -- via the "biotin" moiety of step b) binding to the “avidin or streptavidin” of step c)?

3) There is no clear nexus between the “enzyme reaction or color reaction” of step f) and what the anti-IgG antibody is "marked" with in step e).

In claim 6, “is used in the detection of dilatative myocardiopathy…”, etc. is indefinite because base claim 1 recites a “Method for detecting disease associated autoantibodies” rather than for detecting the “disease” per se. It is therefore believed that claim 6 should recite --is used in the detection of autoantibodies associated with dilatative myocardiopathy…, etc--.

The Markush group of claim of claim 6 is improper by virtue of doubly reciting one of the diseases. Line 4, recites “dilatative myocardiopathy” and line 5 recites “dilatative cardiomyopathy”. Are not these the same? Assuming that these are the same, one of these members must be deleted (it is believed that dilatative

cardiomyopathy" is the art recognized term), and all of claims 5, 7, 9 and 33 must be checked and amended, if necessary, in order to be consistent with claim 6.

In claim 9, at the right-hand end of each line commencing with "in the case of", it is believed that "are used" should be recited as –are detected--.

Claim 10 fails to provide any nexus between the "denaturing agent" and/or the "precipitated fraction" of base claim 1, steps a) and b), and the manner in by which "autoantibodies are concentrated or purified" in claim 10.

In claim 10, "being identified" is unclear because base claim 1 has referred to a "Method for detecting disease associated autoantibodies" rather than for "identifying" autoantibodies.

In claim 11, line 3 "the method for concentrating or purifying" lacks antecedent basis. It is believed that dependency from claim 10, rather than claim 1, is intended.

In claim 11, applicant has lettered the recited steps as "a)" through "d)". It is thus unclear whether these are intended to be further descriptions of steps "a)" through "d)" of base claim 1, or whether these are intended to precede step "a)" of base claim 1.

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: it is unclear how the "peptide" of step "b)" is related to the "carrier" of step "c)". Is the former coupled/adsorbed to the latter at the start of step "b)"? It is also unclear whether the "carrier" of claim 11, step c) is the same carrier as that of base claim 1, step c).

In claim 12, the Markush group of peptides in part "a)" is improper. The phrase "the group comprising" must be replaced with the phrase -- the group consisting of --.

The Markush group of claim 13, is improper because not all members are functional equivalents. Rather, it appears that applicant has contemplated numerous members that would inherently relate to diverse functions. First of all, it appears that the "biotin groups" would be obligatory, in order for the peptide to be captured onto the "carrier coated with avidin or streptavidin" that has been recited in step c) of base claim 1 (see 112, 1st rejection infra). Secondly, if one assumes that the "biotin groups" have

a function pertaining to capturing (e.g. are the "biotin goups" of claim 13 the same as the "biotin" of claim 1, step b)?), then numerous other Markush group members have entirely different functions, as implied by their very names – e.g. "markers, spacers". Additionally, at least one of members has no clear function at all; any peptide inherently has amide bonds between the amino acid residues; therefore, what is the point of reciting "amides"?

In claim 14, line 3 "the linker and/or the spacer" lacks antecedent basis. It is believed that dependency from claim 13, rather than claim 1, is intended.

The Markush group of claim 13, is improper because the member "translocations" refers to a modification that can occur in genes encoding a polypeptide antigen, rather than to modifications of the polypeptide per se.

In claim 32, the Markush group of peptides in part "a)" is improper. The phrase "the group comprising" must be replaced with the phrase -- the group consisting of --.

Claims 32 and 35 each provide for "the step of using" a peptide, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 32 and 35 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

REJECTION(S) UNDER 35 USC 112, FIRST PARAGRAPH

Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the case in which one uses an agent for precipitating autoantibodies, does not reasonably provide enablement for the case in

which one uses a denaturing agent, in step a) of claim 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The scope of "denaturing" agents is extremely broad and would include numerous agents which would denature any autoantibody to the extent that it would not be able to bind to its cognate autoantigen. In such case, any autoantibodies originally present in a bodily fluid sample would be rendered incapable of being detected. It is considered that applicant's disclosure could support the recitation of – a precipitating agent for autoantibodies– in claim 1, step a). See spec. page 6, 2nd full para., particularly the last sentence thereof. It is considered that those of skill in the art would know what the genus of precipitating agents encompasses, since such agents have been conventionally used in the art of immunoglobulin purification.

Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the case in which the peptide used in step b) of claim 1 is a peptide comprising biotin, does not reasonably provide enablement for the case in which the peptide used in step b) of claim 1 is a peptide lacking biotin. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

It has been noted supra, regarding 112, 2nd issues, that in claim 1, step b), the phrase "particularly one" renders the claim indefinite because it is unclear whether the peptide is a peptide comprising biotin or not comprising biotin. The Office takes the position that the peptide used in step b) of claim 1 must be a peptide comprising biotin because claim 1, step c) requires that the "mixture" formed in step b) be incubated "with a carrier coated with avidin or streptavidin." If the peptide is a peptide not comprising biotin, how then does the "mixture" formed in step b) become captured by the "carrier" of step c)?

Applicant must correct by either:

1) amending claim 1, step b) to require a peptide comprising biotin, or

2) amending claim 1, steps b) and c) to more broadly refer to a peptide comprising a tag and a carrier coated with an anti-tag, in a manner that can be supported by the para. spanning spec. pp 5-6.

Claim 15 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant was not in possession of the genus of peptides that have been "modified by means of a deletion, addition, substitution, translocation, inversion and/ or insertion" as recited in claim 15.

Since the substitution of a single amino acid within any given parent polypeptide sequence can abolish the binding of an antibody thereto (Lederman et al, Molec. Immunol. 28, 1171-1181, 1991, cited on PTO-892), the use of a peptide other than one having a naturally occurring sequence from "the first and/or second loop" would not likely provide a peptide which would serve as a cognate antigen for detecting disease associated autoantibodies. This position will be maintained irrespective of whether the modification is substitution, or alternatively, one or more of a deletion, translocation, inversion and insertion. The only possible modification that one of skill could readily envision would be that one could add on flanking residues, such as residues which naturally occur, within the "the first and/or second loop", on one or both sides of an identified epitopic peptide sequence, or such as the residues of a fused tag/flag sequence, or such as a single Cys residue (e.g. for covalently coupling the peptide to a carrier) However, the examiner cannot determine whether applicant has described these kinds of additions. On the other hand, applicant has given the public no direction as to where, within any of the exemplified epitopic peptide sequences, modifications can be made, of any kind, that would permit the peptide to retain its capacity to serve as a cognate antigen for detecting disease associated autoantibodies. One of skill, given any

one of the exemplified peptide sequences, thus would not be able to determine which peptides, having one or more modification(s) within their internal sequence, would be members of the genus of useable peptides that would serve as cognate antigens for detecting disease associated autoantibodies.

Claims 13-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant has not disclosed how one is to use the various “linkers and spacers” of dependent claims 13-14 in the method of base claim 1. If one assumes that the peptide of base claim 1, step b) has a “biotin” which would be captured by the carrier coated with avidin or streptavidin in step d), why then dose one need linkers/spacers? There would be no need to link the biotinylated peptide to a carrier, because the “biotin” will do that. If in claim 1, step e), "the anti-IgG antibody is marked", why then would one need a link the peptide to another marker/label? Applicant has not positively indicated any other kind of moiety that one would need to link the peptide to, in order to conduct the detecting method of base claim 1.

REJECTION(S) UNDER 35 USC 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 32 And 35 Are rejected under 35 U.S.C. 102(b) or (e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over either Wallukat et al, (J. Molec. Cell. Cardiol. 1995, cited on PTO-892) or Ronspeck et al (WO 01/21660 or US 6,994,970, latter cited on PTO-892).

The US and foreign references of Ronespeck et al have the same disclosure. For convenience the examiner will refer to the US document by col. and line number. Only the US document is supplied, since the instant applicant is a co-inventor with Ronespeck.

Wallukat et al teach the peptide sequences which constitute the dominant autoantibody-reactive epitopes of the first and second extracellular loops of the β1 adrenoreceptor (andrenegen receptor). These are identical to the peptides having instant SEQ ID NOS: 2 and 3. Wallukat et al note that earlier investigators have shown that the sera of DCM patients contains autoantibodies that react with peptides derived from the first and second extracellular loops of the β1 adrenoreceptor (p 398, col. 2).

Ronspeck et al teach the same epitopic sequences as Wallukat et al, except that Ronspeck et al provide these peptides with flanking sequences derived from the first or second extracellular loops of the β1 adrenoreceptor. Ronspeck et al conduct an ELISA assay for autoantibodies in the sera of DCM patients. See col. 8, lines 11-44. Therein Ronspeck et al refer to the teachings of Wallukat et al regarding assays. Neither the Wallukat et al nor Ronspeck et al references teach the precise method by which they conducted assays for autoantibodies in the sera of DCM pateints. However, the claims do not require any particular immunoassay format, and do not require the use of any particular reagent, except for one or more of the recited peptides. Since each of the

references teaches the peptides, claims 32 and 35 are anticipated or, at the least, would have been obvious.

Claims 1-8, 10-13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wallukat et al, (J. Molec. Cell. Cardiol. 1995, cited on PTO-892) and Ronspeck et al (WO 01/21660 or US 6,994,970, latter cited on PTO-892), both in view of Aalberse (US 4,468,470, cited on PTO-892).

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Aalbrese teaches a format for conducting an assay for antibodies against an antigen. In this format, soluble antigen coupled to biotin (or a hapten), is incubated with a body fluid sample possible containing antigen-reactive antibodies. Following incubation, the sample is then added to an insoluble/carrier/solid phase-bound avidin (or anti-hapten antibody). Any complexes of avidin-biotinylated antigen-sample antibody are detected by the addition of a labeled anti-Ig antibody. See col. 2, line 1-col. 3, line 3. The label of the anti-Ig antibody can be any conventional label, such as an enzyme (col. 1, lines 19-22).

It would have been obvious to detect autoantibodies in the sera of DCM patients by using biotinylated derivatives of the peptides taught by Wallukat et al and Ronspeck

et al according to the assay format of Aalberse. The assay of Aalberse is a known assay for detecting antibodies. Autoantibodies react with their cognate antigens in the same manner as other antibodies. From the teachings of Ronspeck et al, that their peptides can be biotinylated (see teachings regarding position “X01” throughout the specification and in claim 1), one of ordinary skill would have fully expected that a biotinylated peptide of Wallukat et al or Ronspeck et al would be capable of binding to both autoantibody and avidin, as would be required when the biotinylated peptide is to be used in an assay having the format taught by Aalberse. The claimed method is thus drawn to using the biotinylated peptides of Ronspeck et al in a known manner which would give an expected result.

With respect to the class of autoantibodies to be detected, neither the Wallukat et al nor Ronspeck et al references particularly mention the class specificity of any labeled anti-Ig reagent that may have been used. Wallukat et al however teach that it is the IgG class of autoantibodies that have a physiologically detrimental effect in the pathogenesis of DCM (p 400, col. 1). Thus it would have further been obvious, when detecting autoantibodies in DCM patients according to the assay format of Aalbrese, to have used a labeled anti-IgG regent in lieu of the labeled anti-Ig reagent of Aalberse.

It is noted, also, that Wallukat et al refer to "titration curves of affinity-purified human antibodies in the enzyme immunnoassay" (p 400, col. 1). Thus there are cases in which one would be motivated to use an affinity purified autoantibody fraction of serum, when one detects autoantibodies from a human by an immunoassay. See p 399, col. 1, under heading “Preparation of the Immunoglobulin fraction and of affinity-purified antibodies” for a disclosure of how to purify autoantibodies. Thus it would have been obvious to have conducted the assays for autoantibody, according to the format of Aalberse by using an affinity purified immunoglobulin fraction of a body fluid sample, instead of an unfractionated body fluid sample.

From the above, instant claims 1-8, 10-13, 15, 32 and 35 would have been obvious.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wallukat et al, and Ronspeck et al, both in view of Aalberse, as applied to claims 1-8, 10-13 and 15, and further in view of Staudt et al (Circulation, 106, 2448, 2002, cited on PTO-892).

Staudt et al show the further feature that when there are autoantibodies directed against an epitope in the first loop of the β1 adrenoreceptor, these are of the IgG3 subclass. It thus would have been obvious that, in cases in which one would be diagnosing the condition of a pateint suspected of having and/or being treated for the presence of such autoantibodies, one could use a more specifically reactive labeled anti-IgG3 antibody in lieu of a more broadly reactive labeled anti-IgG antibody.

With respect to the rejection of claim 9, Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

CONTACTS

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, whose telephone number is 571-272-0849. The examiner can normally be reached on Mon.-Thu. from 8:00 am to 5:30 pm and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara, can be reached on 571-272-0878. The fax phone number for the organization where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Typed 9/13/08 DAS

/David A Saunders/

Primary Examiner, Art Unit 1644